Comparison of CDPH Guidelines and CIRM Regulations

CDPH Guidelines for HSCR	CIRM Regulations	Differences/Considerations for Committee Review
§4(a)- A SCRO Committee shall include at least one non-scientist member of the public who is not employed by, *or appointed to, or remunerated by the relevant research institution*, and who is not part of the immediate family of a person who is affiliated with the institution.	§100060(a)- A SCRO committee shall include at least one non-scientist member of the public who is not employed by, or part of the immediate family of a person who is affiliated with the institution.	-CIRM regulation no longer contains prohibition of remuneration. • Should CDPH change the qualifications of the SCRO Committee non-scientist member?
§5(d)- refers to SCRO Committee review of clinical trials	N/A	-CIRM intends to amend their Regulations to allow IRBs to perform review of clinical trials • Should the Guidelines be amended to allow IRBs instead of SCROs to review clinical trials involving the use of human pluripotent cells or cells derived from human pluripotent cells?
§6(a)(1)- refers to recognized authorities	§100080(a)(F)- Be derived under license of the Australian National Health and Medical Research Council	• CDPH can amend the Guidelines to include the Australian National Health and Medical Research Council as a recognized authority
§7 – refers to additional requirements for deriving new covered stem cell lines	§100080(b)- refers to additional requirements for derivation and use of all covered stem cell lines	-CDPH Guidelines require SCRO Committees to confirm donors of human gametes, embryos, somatic cells or tissue have given voluntary and informed consent -CIRM requires derivation of new stem cell lines to adhere to restrictions regarding days in culture and payment • Should CDPH include additional specific requirements in §7 for derivation of new human stem cell lines?
§10(b)(2)- Researchers shall offer donors an opportunity to *document their preferences* regarding future uses of their donated materials. Researchers may choose to use materials only from donors who agree to all future uses.	§100100(b)(2)- A donor must be given the opportunity to *impose restrictions* on future uses of donated materials. Researchers may choose to use materials only from donors who agree to all future uses *without restriction*.	• Should Guidelines be revised to match CIRM language?